

(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Sheffield et al.

Application No.: 10/731,892

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Art Unit: 3766

For: METHODS FOR TREATING AND/OR
COLLECTING INFORMATION REGARDING
NEUROLOGICAL DISORDERS,
INCLUDING LANGUAGE DISORDERS

Examiner: J. L. Reidel

DECLARATION OF ALLEN WYLER, M.D., UNDER 37 C.F.R. SECTION 1.132

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Allen Wyler, declare that:

(1) I am a citizen of the United States residing at 2319 First Avenue No. 405, Seattle, WA 98121.

(2) I have been an employee of Northstar Neuroscience since 2002, holding the position of Medical Director.

(3) My professional qualifications and relevant professional experience are detailed in the attached curriculum vitae.

(4) My surgical practice specialty is the neurosurgical treatment of epilepsy.

(5) I am familiar with existing deep brain stimulation (DBS) techniques used to treat neurological disorders. I am also familiar with cortical stimulation techniques that have been developed and are currently being developed by Northstar Neuroscience for treating neurological disorders.

(6) DBS is generally much more invasive than cortical stimulation because DBS requires that an electrode be passed through cortical as well as deep brain tissue until the electrode is located within specific deep brain tissue. Cortical stimulation is applied from electrodes implanted proximate to the dura mater surrounding the brain, but outside the cortical surface of the brain. Cortical stimulation is thus *extra-cerebral*. In contrast, DBS is applied to deep neural structures that are *intra-cerebral*.

(7) The application of an extra-cerebral signal outside a cortical surface of the brain is not identical to or a simple or straightforward equivalent of the application of an intra-cerebral signal to a deep brain structure.

(8) A current applied by an intra-cerebral DBS electrode to a deep brain structure can activate deep brain neurons that reside adjacent to or in the immediate proximity of the DBS electrode. In particular, those deep brain neurons that are directly affected by the DBS current are unlikely to reside more than a few millimeters away from the DBS electrode. The activation of such deep brain neurons can result in the generation of action potentials that propagate away from these deep brain neurons along axonal pathways and possibly intermediary neural structures. Such action potentials can travel to portions of particular cortical structures. However, this type of indirect effect upon cortical neurons is not equivalent to or a simple substitute for the direct electrical stimulation of cortical neurons using an extra-cerebral electrode, that is, an electrode implanted proximate to the dura mater and outside a cortical surface of the patient's brain.

(9) Even when a cortical stimulation structure for treating a particular type of neurologic dysfunction is defined, DBS stimulation parameters for effectively treating such neurologic dysfunction may not be, and generally are not, the same as or even indicative of the cortical stimulation parameters for effectively treating the neurological disorder. For a particular type of neurologic disorder or patient symptom, a given set or range of efficacious DBS stimulation parameters can have no beneficial effect, or result in an adverse effect, when used to treat the disorder or symptom using cortical stimulation.

(10) U.S. Patent No. 5,938,688 to Schiff provides a representative example of the foregoing state of the art at the time of the invention by disclosing the intralaminar nuclei (which are deep brain structures) as the preferred region to which electrical stimulation is to be applied, to the exclusion of other regions of the patient's brain.

(11) Based on the foregoing, many applications of cortical stimulation techniques are not equivalent to or otherwise interchangeable with DBS techniques; cortical stimulation techniques, therefore, are not readily substituted for existing DBS techniques. Any consideration of whether to treat a patient using an extra-cerebral signal applied by way of an electrode implanted proximate the dura mater and outside a cortical surface, versus an intra-cerebral signal applied by way of a DBS electrode, is not simply an arbitrary design consideration.

(12) I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.



Allen Wyler, M.D.

Address: at 2319 First Avenue No. 405, Seattle, WA 98121

Date: 11/05/07

CURRICULUM VITAE

NAME: Allen R. Wyler, M.D.
BIRTHDATE: September 3, 1943
BIRTHPLACE: Seattle, Washington

CURRENT POSITION: Medical Director, Northstar Neuroscience Inc

EDUCATION:

Undergraduate:	BA, University of Washington, Seattle, WA	1961-1965
Graduate/Medical School:	M.D., University of Washington, Seattle, WA	1965-1969
Honors:	John and Mary Wilson Scholarship O'Donnell Award, University of Washington Medical Thesis, University of Washington Teacher Investigator Award - NIH	1967-1969 1969 1969 1977-1983
Internship:	General Surgery, University of Washington Seattle, Washington	1969-1970
Residency:	Neurosurgery, University of Washington Seattle, Washington	1970-1974
MILITARY SERVICE:	United States Army	1969-1981
BOARD CERTIFICATION:	Diplomate of National Board of Medical Examiners American Board of Neurological Surgery	1970 1978
MEDICAL LICENSURE:	State of Washington Tennessee Arkansas Mississippi	1970-present 1984-1992 1984-1992 1984-1992 1989-1992

CURRENT SOCIETY MEMBERSHIPS:

American Association of Neurological Surgeons
The Society of Neurological Surgeons
The American Academy of Neurological Surgery
King County Medical Society
Hong Kong Neurosurgical Society (Honorary member)

UNIVERSITY APPOINTMENTS:

Acting Instructor, University of Washington, Neurological Surgery	1974-1975
Assistant Professor, University of Washington, Dept. Neurological Surgery	1975-1981
Chief of Neurosurgery, Harborview Medical Center, Seattle, Washington	1977-1984
Associate Professor, University of Washington, Dept. of Neurological Surgery	1981-1984
Professor, University of Tennessee-Memphis, Dept. of Neurosurgery	1984-1992
Professor, University of Tennessee-Memphis, Dept. of Anatomy & Neurobiology	1986-1992
Vice-Chairman University of Tennessee-Memphis, Dept. of Neurosurgery	1985-1992

CURRENT HOSPITAL APPOINTMENTS:

Swedish Medical Center/Seattle	1992 - present
Medical Director, Epilepsy Center, Seattle WA	1992 - 2002
Executive Director, Neuroscience Institute	1996 - 2002

EDITORIAL APPOINTMENTS:

Book Review Editor, <i>Epilepsia</i>	1980 - 1981
Editor-in-Chief, <i>Journal of Epilepsy</i> ,	1987 - 1998
Member, Editorial Board, <i>Acta Neurologica Scandinavica</i> ,	1996 - present
Member, Editorial Board, <i>Surgical Neurology</i>	1996 - present
Neurosurgery section editor, e-Medicine	2000 - present

COMMITTEES AND OFFICES HELD:

Veterans Administration - Neurobiology Study Section	1980-1987
Epilepsy Foundation of America Study Section	1982-1989
Professional Advisory Board: Epilepsy Foundation of America	1982-1989
Professional Advisory Board: Epilepsy Foundation of West Tennessee	1989-1992
National Association of Epilepsy Centers	
Secretary-Treasurer	1988
Vice-President	1989-1992
Board of Directors	1988-1992

PUBLICATIONS (JOURNALS):

1. Wyler AR, Masuda M, Holmes TH. Seriousness of illness rating scale. *J Psychosom Res* 11:363-374, **1968**.
2. Wyler AR: Life events and seriousness of illness. *Medical Thesis*, University of Washington, **1969**.
3. Wyler AR, Masuda M, Holmes TH. The seriousness of illness rating scale: Reproducibility. *J Psychosom Res* 14:59-64, **1970**.
4. Wyler AR, Masuda M, Holmes TH. Magnitude of life events and seriousness of illness. *Psychosom Med.* 33:115-122, **1971**.
5. Wyler AR and Chatrian GE. Positive bursts (14- and 6- per second positive spikes) in a patient with a penetrating wound of the brain. *EEG and Clin Neurophysiol* 32:317-321, **1972**.
6. Wyler AR and Kelly WA. Use of antibiotics with external ventriculostomies. *J Neurosurgery* 37:185-187, **1972**.
7. Wyler AR, Fetz EE, Ward AA, Jr. Spontaneous firing patterns of epileptic neurons in the monkey motor cortex. *Exp Neurol* 40:567-585, **1973**.
8. Fetz EE and Wyler AR. Operantly conditioned firing patterns of epileptic neurons in the monkey motor cortex. *Exp Neurol* 40:586-607, **1973**.
9. Wyler AR and Harris AB. Recurrent desmoid tumor following cervical laminectomy. *J Neurosurg* 39:114-116, **1973**.
10. Wyler AR, Smith HJ Jr., Loeser JD. Subarachnoid hemorrhage in infancy due to brain tumor. *Arch Neurol* 29:447-448, **1973**.
11. Wyler AR, Fetz EE, Ward AA Jr. Injury-induced long-first-interval bursts in cortical neurons. *Exp Neurol* 41:773-776, **1973**.
12. Wyler AR and Harris AB. Cerebellar ataxia with mycoplasma pneumonia. *Ann Int Med* 80:556, **1974**.
13. Wyler AR and Fetz EE. Behavioral control of firing patterns of normal and abnormal neurons in chronic epileptic cortex. *Exp Neurol* 42:448-464, **1974**.
14. Wyler AR, Fetz EE, Ward AA Jr. Antidromic and orthodromic activation of epileptic neurons in neocortex of awake monkey. *Exp Neurol* 43:59-74, **1974**.
15. Kusske JA, Wyler AR, Ward AA Jr. Tungstic acid gel as a focal epileptogenic agent. *Exp Neurol* 42:587-592, **1974**.
16. Wyler AR. Epileptic neurons during sleep and wakefulness. *Exp Neurol* 42:593-608, **1974**.
17. Wyler AR, Fetz EE, Ward AA Jr. Effects of operantly conditioning epileptic unit activity on seizure frequencies and electrophysiology of neocortical experimental foci. *Exp Neurol* 44:113-125, **1974**.
18. Wyler AR, Leech RW, Reynolds AF, Ojemann GA, Mead C. Cholesterol granulomas of the petrous apex. *J Neurosurg* 41:765-768, **1974**.

19. Wyler AR, Fetz EE, Ward AA Jr. Firing patterns of epileptic and normal neurons in the chronic alumina focus in undrugged monkeys during different behavioral states. *Brain Res* 98:1-20, 1975.
20. Wyler AR, Wilkus RJ, Troupin AS. Methysergide in the treatment of narcolepsy. *Arch Neurol* 32:265-268, 1975.
21. Wyler AR, Loeser JD, Killien FC. Septum posticum cysts: an uncommon cause of chronic back pain. *Pain* 1:271-275, 1975.
22. Mesher RA and Wyler AR. Burst structure in developing penicillin epileptic feline foci. *Exp Neurol* 51:457-467, 1976.
23. Wyler AR, Lockard JS, Ward AA Jr., Finch CA. Conditioned EEG desynchronization and seizure occurrence in patients. *EEG Clin Neurophys* 41:501-512, 1976.
24. Wyler AR and Primm MM. Operant conditioning of tonic neuronal firing rates from single units in monkey motor cortex. *Brain Res* 117:498-502, 1976.
25. Reynolds AF Jr., Wyler AR, Norris HT. Paraparesis secondary to sodium urate deposits in the ligamentum flavum. *Arch Neurol* 33:795, 1976.
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28. Wyler AR and Reynolds AF. An intracranial complication of nasogastric intubation. *J Neurosurg* 47:297-298, 1977.
29. Wyler AR and Lockard JS. Seizure severity and acquisition and performance of operant tasks in a monkey model. *Epilepsia* 18:109-116, 1977.
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32. Wyler AR, Lockard JS, DuCharme LL, Perkins MG. EEG operant conditioning a monkey model: II. EEG spectral analysis. *Epilepsia* 18:481-488, 1977.
33. Rapport RL, Ojemann GA, Wyler AR, Ward AA Jr. Surgical management of Epilepsy. *Western J Med* 127:185-189, 1977.
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35. Wyler AR and Finch CA. Operant conditioning of tonic firing patterns from precentral neurons in monkey neocortex. *Brain Res* 146:51-68, 1978.
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37. Wyler AR. Single unit analysis of "mirror foci" in chronic epileptic monkeys. *Brain Res* 150:201-204, 1978.
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40. Wyler AR, Burchiel KJ, Ward AA Jr. Chronic epileptic foci in monkeys: correlation between seizure frequency and proportion of pacemaker epileptic neurons. *Epilepsia* 19:475-483, 1978.
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54. Wyler AR and Ward AA Jr. Cranial asymmetry secondary to unilateral hemispheric damage during late childhood. *J Neurosurg* 52:423-425, 1980.

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71. Wyler AR, Ojemann GA, Ward AA Jr. Neurons in human epileptic cortex: correlation between unit and EEG activity. *Ann Neurol* 11:301-308, 1982.
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73. Wyler AR. Neuronal activity during seizures in monkeys. *Exp Neurol* 76:574-585, 1982.

74. Wyler AR and Bolender NF. Preoperative CT diagnosis of mesial temporal sclerosis for surgical treatment of epilepsy. *Ann Neurol* 13:59-64, 1983.
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79. McLean A Jr., Dikmen S, Temkin NR, Wyler AR, Gale JL. Psychosocial functioning at one month after head injury. *Neurosurg* 14:393-399, 1984.
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83. Mateer CA, Kettrick C, Wyler AR. Disruption of sign language production with nondominant cortical stimulation: further evidence for bilateral control. *Brain and Lang.* 21:132-135, 1984.
84. Dikmen S, Temkin NR, Weiler M, Wyler AR. Behavioral effects of anticonvulsant prophylaxis: no effect or artifact? *Epilepsia* 25:741-746, 1984.
85. Wyler AR. Synchrony between cortical neurons during operant conditioning. *Brain Res* 341:66-72, 1985.
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89. Wyler AR, Ray MW. Aphasia for Morse code. *Brain and Lang* 27:195-198, 1986.
90. Slimp JC, Tamas LB, Stolov WC, Wyler AR. Somatosensory evoked potentials after removal of sensory cortex in man. *EEG Clin Neurophys* 65:111-117, 1986.
91. Wyler AR. Synchrony between cortical neurons in normal and epileptogenic cortex of monkey. *Epilepsia* 27:171-176, 1986.
92. Dikmen S, McLean A Jr., Temkin NR, Wyler AR. Neuropsychologic outcome at one-month postinjury. *Archives Physical Med and Rehabil* 67:507-13, 1986.

93. Dodrill CB, Wilkus RJ, Ojemann GA, Ward AA Jr., Wyler AR, Van Belle G, Tamas LB. Multidisciplinary prediction of seizure relief from cortical resection surgery for epilepsy. *Ann Neurol* 20:2-12, 1986.
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96. Hermann BP, Wyler AR, Richey ET, Rea JM. Memory function and verbal learning ability in patients with complex partial seizures of temporal lobe origin. *Epilepsia* 28:547-554, 1987.
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98. Hermann BP and Wyler AR. Neuropsychological outcome of anterior temporal lobectomy. *J Epilepsy* 1:35-45, 1988.
99. Hermann BP and Wyler AR. Effects of anterior temporal lobectomy on language function: a controlled study. *Ann Neurol* 23:586-588, 1988.
100. Hermann BP, Whitman S, Wyler AR, Richey ET, Dell J. The neurological psychosocial and demographic correlates of hypergraphia in patients with epilepsy. *J Neurology, Neurosurgery, and Psychiatry* 51:203-208, 1988.
101. Hermann BP, Wyler AR, Richey ET. Wisconsin Card Sorting Test performance in patients with complex partial seizures of temporal-lobe origin. *Journal of Clinical and Experimental Neuropsychology* Vol. 10, 4:467-476, 1988.
102. Hermann BP, Wyler AR, Steenman H, Richey ET. The interrelationship between language function and verbal learning/memory performance in patients with complex partial seizures. *Cortex* 24:245-253, 1988.
103. Hermann BP and Wyler AR. Comparative results of dominant temporal lobectomy under general or local anesthesia: language outcome. *J Epilepsy* 1:127-134, 1988.
104. Steenman HF, Hermann BP, Wyler AR, Richey ET. The MacAndrew Alcoholic Scale in Epilepsy: a high false positive error rate. *J Clin Psychol* 44:457-460, 1988.
105. Wyler AR, Walker G, Richey ET, Hermann BP. Chronic subdural strip electrode recordings for difficult epileptic problems. *J Epilepsy* 1:71-78, 1988.
106. Wyler AR, Richey ET, Atkinson RA, Hermann BP. Strip electrodes in acute electrocorticography. *J Epilepsy* 1:95-97, 1988.
107. Wyler AR and Hermann BP. Comparative results of temporal lobectomy under local or general anesthesia: seizure outcome. *J Epilepsy* 1:121-125, 1988.
108. Wyler AR, Richey ET, Hermann B. Comparison of scalp to subdural recordings for localizing epileptogenic foci. *J Epilepsy* 2:91-96, 1989.
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